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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/726,550	12/04/2003	Osamu Kanie	P24643	5494
7055	7590	07/05/2006	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			SHAMEEM, GOLAM M	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/726,550

Applicant(s)

KANIE ET AL.

Examiner

Golam M. M. Shameem, Ph.D.

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 6-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 09/03/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

This application is a CIP of PCT/JP02/05672 06/07/2002 and the claim of foreign priority under 35 U.S.C. § 119(a)-(d) to Japan 2001-173855 06/08/2001 is acknowledged.

### ***Status of Claims***

Claims 1-11 are currently pending in the application.

Receipt is acknowledged of amendment / response filed on May 03, 2006 and that has been entered.

Claims 6-11 are withdrawn from further consideration pursuant to 37 C.F.R. 1.142 (b) as being drawn to a non-elected subject matter.

### ***Information Disclosure Statement***

Receipt is acknowledged of Information Disclosure Statement (IDS), filed on 09/03/2004, which has been entered in the file.

### ***Response to Election/Restriction***

In response to the restriction requirement, Applicants have elected Group I, which includes claims 1-5 drawn to a compound of formula (I) with traverse is acknowledged. The traversal is on the ground(s) that all the pending claims should be rejoined and examined with the elected Group I because "the Examiner has not pointed to any evidence of a serious search burden" (Remarks, page 3) and therefore, a search and examination of the entire application should be made without a serious burden.

Applicant's arguments are fully considered and found unpersuasive because the products of Invention groups I-IV differ materially in structure and in element from each other and

therefore, are capable of supporting their own patents. The invention groups I-IV are related to a set of structurally diverse compounds, process for preparation and their methods of uses (chemical structures, which are similar, are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly), which do not possess a substantial common core wherein a reference anticipating one would not necessarily render the other obvious and to search all the above groups in a single application would be an undue burden on the Examiner. Because of many classes and subclasses in each of the Group, a separate search considerations are involved, which would impose a serious burden on the Examiner to perform a complete search of the defined areas if unrestricted. Also the fields of search are not coextensive. The wide disparity among the groups requires that many divergent fields must be searched, including all classes and subclasses of U.S. and foreign patents as well as journals and publications. Moreover, the Examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the Examiner. Nevertheless, Examiner may reconsider to rejoin process / method of use claims commensurate in scope with the product claims when the case would be found in condition for allowance [provided those process / method claims are free from 35 U.S.C. §112 first (including written description, reach-through claim language and/or scope-enablement issues) and second paragraphs]. For these reasons, Applicant's arguments are found unpersuasive and, therefore, the requirement for restriction and election of species is still deemed proper.

Applicants preserve their right to file a divisional on the non-elected subject matter.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wrodnigg *et al* (1997). Applicant claims azasugar compounds, process of making and their methods of uses thereof. Wrodnigg *et al* (1997) also disclose the synthesis of several substituted pyrrolidinediol derivatives and at least one of them anticipates the instantly claimed invention of formula (I), wherein  $R^1$  is hydrogen,  $R^2$  is substituted alkyl group (such as,  $CH_2OR^{12}$  wherein  $R^{12}$  is hydrogen, claim 5),  $R^3$  and  $R^4$  are independently hydrogen, X represents  $-N(R^5)R^6$  [wherein  $R^5$  and  $R^6$  are independently hydrogen] and Y is hydrogen atom [STN International, HCAPLUS database, RN number, 194288-65-8 and 194288-74-9, a copy is provided with this Office action], which read on the instantly claimed compounds.

Claims 1-5 are rejected under 35 U.S.C. § 102(b) as being anticipated by Barta *et al* (1995). Barta *et al* also disclose the synthesis of several substituted iminosugars as glycosidase inhibitors and at least one of them anticipates the instantly claimed invention of formula (I), wherein  $R^1$  is a  $C_{1-10}$  alkyl group (such as n-butyl),  $R^2$  is substituted alkyl group (such as,  $CH_2OR^{12}$  wherein  $R^{12}$  is hydrogen, claim 5),  $R^3$  and  $R^4$  are independently hydrogen, X represents  $-N(R^5)R^6$  [wherein  $R^5$  and  $R^6$  are independently hydrogen] and Y is hydrogen atom [STN International, HCAPLUS database, RN number, 172936-42-4, a copy is provided with this Office action], which read on the instantly claimed compounds.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claim in the subject matter, which the applicant regards as his invention.

Claims 1-5 are rejected under 35 USC § 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression “a residue”, [claim 1 (Original), line 7, page 2 and all other occurrences, if any], renders the claims indefinite because of connoting no information as to which portion of the molecule remains and therefore it is unclear what applicant is intending to encompass with this expression. The above expression is not defined in the claims so as to ascertain the metes and bounds of the claimed subject matter. The omission of failing to describe the claimed invention renders the claims incomplete. This rejection can be overcome by deleting the phrase or to amend the claim (“residue” may be replaced with the expression ‘group’) within the context and scope of the claim in order to overcome the rejection.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Golam Shameem, Ph.D. whose telephone number is (571) 272-0706. The examiner can normally be reached on Monday-Thursday from 6:30 AM - 5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane, can be reached at (571) 272-0699. The Unofficial fax phone number for this Group is (703) 308-7921. The Official fax phone numbers for this Group are (571)-273-8300.

When filing a FAX in Technology Center 1600, please indicate in the Header (upper right) "Official" for papers that are to be entered into the file, and "Unofficial" for draft documents and other communications with the PTO that are not for entry into the file of the application. This will expedite processing of your papers.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [joseph.mcKane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (571) 272-1600.

Golam M M Shameem, Ph.D.  
Primary Examiner  
Art Unit 1626  
Technology Center 1600



**GOLAM M. M. SHAMEEM, PH.D**  
**PRIMARY EXAMINER**

May 23, 2006